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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/510,368	LEFERE ET AL.	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-17,19-23 and 25* is/are rejected.

7)☒ Claim(s) *5,18,24, and 26-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Claims 5, 18, 24, and 26-27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Vining et al. (US Patent No. 5,782,762).

Regarding claim 19, Vining et al. disclose a method for generating a three-dimensional rendering of a patient's colon, wherein the patient initially undergoes a preparation procedure which includes cleansing of the colon (column 2, lines 35-53). They further disclose that as an alternative to a cleansing procedure that requires a liquid diet and laxatives, a low residue diet (i.e. food items) maybe be fed to the individual combined with a contrast agent, such as a low density barium (column 8, lines 13-20). This may serve to opacify any retained stool (column 8, lines 17-20).

Regarding claim 20, Vining et al. disclose that this low residue diet combined with the contrast agent is given to the individual for about three days before imaging the colon.(i.e. food items are administered over at least a 24-hour period before the predetermined activity).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US Patent No. 6,331,116) in view of Cittadini et al. ("Bowel Preparation for the Double-contrast Barium Enema: How to Maintain Coating with Cleansing?", 1999).

Regarding claim 1, Kaufman et al. disclose a system and method for performing a volume based three-dimensional virtual examination, such as a virtual endoscopy, using planned and guided navigation techniques (column 1, lines 14-19). They disclose a bowel preparation step in their method prior to performing the CT MRI scan of the colon (i.e. predetermined activity) (column 16, lines 37-43). They further disclose that an exemplary bowel preparation operation includes ingesting three 250 cc doses of Barium Sulfate suspension of 2.1% W/V during the day (i.e. 24 hour administration period) prior to the imaging scan (column 16, lines 43-49). The Barium Sulfate acts as a tagging marker of the colonic residue in the individual's digestive tract (column 16, lines 49-50). Kaufman et al. disclose that the bowel preparation operation can obviate the need for conventional colonic washing protocols, which can call for the ingestion of laxatives, such as Golytely, prior to a CT scan (column 16, lines 64-67). They further disclose that fluid intake is preferably increased during this time period (column 16, lines 51-54). However, they do not specifically disclose that 1 to 4 liters of total fluid is administered during this time period.

Cittadini et al. disclose a study to assess the value of prior administration of sennosides to obtain a clean colon with a reduced volume of polyethylene glycol (PEG)-saline solution, but maintaining good mucosal coating (abstract).

They separated patients into three groups to receive one of the large bowel cleansing preparations below on the day preceding the examination (pg. 217, Materials and Methods). They disclose that one group received 2 liters of water (pg. 217, Materials and Methods). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Kaufman et al. to administer to the patient 2 liters of fluid, which is within the 1-4 liters of fluid range. The motivation for doing so would have been to provide oral hydration, as taught by Cittadini et al. (pg. 217, Materials and Methods).

Regarding claim 2, as discussed above, Kaufman et al. disclose that they administer 3 doses of the Barium Sulfate suspension (i.e. tagging agent), with the volume of each dose being 250 cc, which falls in the range 25 to 250 mL. Further, Kaufman et al. disclose that the patient receives 2 liters of water, which falls within the 1-3 liters of fluid range.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Cittadini et al. as applied to claims 1-2 above, and further in view of Johnson et al. (US Patent No. 6,477,401).

As discussed above, the combined references of Kaufman et al. in view of Cittadini et al. meet the limitations of claim 1. As discussed above, Kaufman et al. disclose that they administer 3 doses of the Barium Sulfate suspension with the volume of each dose being 250 cc. Cittadini et al. further disclose that a single dose of a 57% w/v suspension of Polibar ACB was administered to the patient.

However Kaufman et al. in view of Cittadini et al. do not specifically disclose that 4 doses are administered to the individual.

Johnson et al. disclose a method for generating colonography images for colorectal cancer screening (column 1, lines 64-66). Their method includes a step of administering a stool marker to the patient followed by imaging of the patient's colon (column 4, lines 13-17). They disclose that the period of administration ranged from 24 to 48 hours prior to imaging while the total number of doses administered ranged from 2 to 7 (column 9, lines 32-42). As can be seen from the chart in Figure 12, one group of individuals received 4 doses. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. in view of Cittadini et al. administer 4 doses of the tagging agent to the individual. The motivation for doing so would have been that the quality of the stool marking improves with a greater quantity of the stool marker administered to the patient, as taught by Johnson et al. (column 10, lines 32-39).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Cittadini et al. as applied to claims 1-2 above, and further in view of Illig et al. (US Patent No. 5,352,434).

As discussed above, Kaufman et al. in view of Cittadini et al. meet the limitations of claim 1. However, they do not specifically disclose that the administration of the tagging agent is 3 doses, wherein the volume of each dose is about 20 mL and comprises about 40 % w/v tagging agent. Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an

effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt. They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (3 doses of a volume of 20 mL can be considered low) (column 9, lines 28-47). They also disclose that the most preferred concentration is from about 15% w/w to about 40% w/w. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. in view of Cittadini et al. to administer 3 doses of tagging agent to the individual wherein the volume of each does is about 20 mL and comprises about 40% w/v tagging agent. The motivation for doing so would have been that this low dosage would reduce the toxicity potential, and 40% w/w is a preferred concentration, as taught by Illig et al. (column 9, lines 28-46).

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Cittadini et al. as applied to claims 1-2 above, and further in view of Illig et al. (US Patent No. 5,260,049).

As discussed above, Kaufman et al. in view of Cittadini meet the limitations of claim 1. However, they do not specifically disclose that the tagging agent is combined with Sorbitol or Mannitol. Illig et al. disclose aqueous compositions containing contrast agents and methods for their use in diagnostic radiology of the gastrointestinal tract (column 1, lines 7-10). They disclose that is

well known in the art that surfactants or emulsifiers (such as sorbitol) combined with the contrast agents can reduce the interfacial tension between two immiscible phases, i.e. oil-in-aqueous medium (column 7, lines 55-59 and column 8, lines 44-56). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Kaufman et al. in view of Cittadini et al. to combine Sorbitol with the tagging agent. The motivation for doing so would have been to reduce the interfacial tension between two immiscible phases, as taught by Illig et al. (column 7, lines 55-59).

11. Claims 7-9, 11, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. (US Patent No. 5,782,762) in view of The Children's Hospital at Westmead Fact Sheet: Low Residue Diet, from now on referred to as CHW (Internet, August 2000, http://web.archive.org/web/20010713061634/http://www.chw.edu.au/parents/factsheets/folowres.htm).

Vining et al. disclose a method and system for generating and displaying interactive, three-dimensional structures, such as the colon (column 5, lines 24-34). The method for imaging the colon includes the initial step of cleansing the colon (column 8, lines 1-4). As an alternative to cleansing the colon, the patient can be fed a low residue diet combined with a contrast agent (i.e. a tagging marker of the colonic residue), such as Barium Sulfate, for about 3 days (column 8, lines 12-20).

However, they do not specifically disclose that this low-residue diet would consist of food items that meet the limitations of claims 7-9 (i.e. comprising 100

calories, at least 0.5 grams of dietary fiber, at least 0.5% of the calories derived from fat, at least 1% by weight of solid material, more than 600 calories, less than about 15 grams of dietary fiber, etc). They also do not specifically disclose that one or more food components are selected from the group consisting of nutritional drinks, beverages, soup products, starch foods, grain foods, protein supplements, fruit foods and vegetable foods. Further, they do not disclose that one or more food items constitute a first feeding, a second feeding, and a third feeding.

CHW disclose a low residue diet to reduce both the number and size of stools (pg.1, lines 8-9). They disclose that foods that are allowed each day for the diet which include foods such as white pasta, white rice, meat, avocado, butter, and pumpkin (Table: Foods allowed each day). The listed allowed foods fall into the groups listed in the instant claim 11. Further, the diet should have 7-10 g of dietary fiber per day (pg.1, line 7). Selection from the foods listed would meet the limitations of claims 7-9 and 11 (i.e. comprising at least 100 calories, at least 0.5 % of calories are derived from fat, from about 600 to about 2000 calories, etc.). With regards to claim 25, CHW disclose a typical daily intake, which consists of breakfast, lunch, and dinner (i.e. first feeding, second feeding, third feeding) (pg. 2). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. to have the low residue diet meet the limitations of instant claims 7-9 and 11. The motivation for doing so would have been to reduce both the number and size of stools, as taught by CHW (pg 1. lines 8-9).

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of CHW as applied to claims 7-9, 11, and 25 above, and further in view of Illig et al. (US Patent No. 5,260,049).

As discussed above, Vining et al. in view of CHW meet the limitations of claim 7. However, they do not specifically disclose that the tagging agent is combined with Sorbitol or Mannitol. Illig et al. disclose aqueous compositions containing contrast agents and methods for their use in diagnostic radiology of the gastrointestinal tract (column 1, lines 7-10). They disclose that is well known in the art that surfactants or emulsifiers (such as sorbitol) combined with the contrast agents can reduce the interfacial tension between two immiscible phases, i.e. oil-in-aqueous medium (column 7, lines 55-59 and column 8, lines 44-56). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Kaufman et al. in view of Cittadini et al. to combine Sorbitol with the tagging agent. The motivation for doing so would have been to reduce the interfacial tension between two immiscible phases, as taught by Illig et al. (column 7, lines 55-59).

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of The Children's Hospital at Westmead Fact Sheet: Low Residue Diet, from now on referred to as CHW, as applied to claims 7-9 and 11 above, and further in view of Cittadini et al..

As discussed above, Vining et al. in view of CHW meet the limitations of claim 7. However, they do not specifically disclose that the total fluid intake by the individual is about 1 to 2 liters. Cittadini et al. disclose that one group that

received a large bowel cleansing preparation was administered 2 liters of water (pg. 217, Materials and Methods). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. in view of CHW to have the total fluid intake by the individual be about 1-2 liters. The motivation for doing so would have been to provide oral hydration, as taught by Cittadini et al. (pg. 217, Materials and Methods).

14. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al..

As discussed above, Vining et al. disclose a method that can be used to display a colon in three dimensions and also in virtual reality (column 7, lines 58-65). As an alternative to bowel cleansing procedures that use a clear liquid diet along with a laxative, Vining et al. disclose feeding the patient a low residue diet combined with a contrast agent, such as Barium, for about three days. After the colon has been cleansed, the colon is then scanned by a helical CT scanner (i.e. CT colonography) to produce a series of 2D images of the colon (column 8, lines 35-48). The radiography images can then be screened to identify the presence of any abnormality in the gastrointestinal tract (column 3, lines 23-44). However, they do not specifically disclose that the screening of the radiography images is done without removing and/or subtracting the marked stool from the images. At the time of the invention, it would have been obvious to one of ordinary skill to screen the radiography images without removing and/or subtracting the marked stool from the images. The motivation for doing so would have been that Vining

et al. do not disclose that this is a necessary step in their method (column 2, line 18- column 3, line 55).

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of Kaufman et al. and further in view of Cittadini et al.

As discussed above, Vining et al. meet the limitations of claim 13. However, they do not disclose the volume of each dose ranging between 25 to 250 mL and that the total fluid intake is 1 to 3 liters over the 20 to 36 hour administration period. Kaufman et al. disclose that in their method of examining the colon, a bowel preparation step is performed which involves administering to the individual three 250 cc doses of Barium Sulfate suspension of 2.1% W/V (column 16, lines 37-63). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. to include the step of administering less than 5 does of Barium Sulfate to the individual, with the volume of each does ranging between 25 to 250 mL as taught by Kaufman et al. The motivation for doing so would have been to create a condition where residual stool and fluid remaining in the colon present significantly different image properties from that of the gas-filled colon interior and colon wall, as taught by Kaufman et al. (column 16, lines 37-63).

However, Vining et al. in view of Kaufman et al. do not specifically disclose that the total fluid intake is 1 to 3 liters over the 20 to 36 hour administration period.

As discussed above, Cittadini et al. disclose that one group that received a large bowel cleansing preparation was administered 2 liters of water (pg. 217,

Materials and Methods). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. in view of Kaufman et al. to have the total fluid intake by the individual be about 1-3 liters. The motivation for doing so would have been to provide oral hydration, as taught by Cittadini et al. (pg. 217, Materials and Methods).

16. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of Kaufman et al. and Cittadini et al. as applied to claims 13-15 above, and further in view of Johnson et al.

Kaufman et al. disclose that 3 doses of 250 mL of Barium Sulfate are given to the individuals (column 16, lines 37-63). Cittadini et al. further disclose that a single dose of a 57% w/v suspension of Polibar ACB was administered to the patient. However, the combined above references do not specifically disclose that 4 doses of the tagging agent are given to the individual.

As discussed above, Johnson et al. disclose that the total number of doses administered ranged from 2 to 7 in their colonography method(column 9, lines 32-42). As can be seen from the chart in Figure 12, one group of individuals received 4 doses. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of the combined above references to administer 4 doses of the tagging agent to the individual. The motivation for doing so would have been that the quality of the stool marking improves with a greater quantity of the stool marker administered to the patient, as taught by Johnson et al. (column 10, lines 32-39).

17. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of Illig et al (US Patent No. 5,352,434). Vining et al. do not specifically disclose that the administration of the tagging agent is 3 doses; wherein the volume of each does is about 20 mL and comprises about 40% w/v tagging agent. Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt (column 3, lines 13-28). They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (3 doses of a volume of 20 mL can be considered low) (column 9, lines 28-47). They also disclose that the most preferred concentration is from about 15% w/w to about 40% w/w (column 9, lines 48-52). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. in view of Cittadini et al. to administer 3 doses of tagging agent to the individual wherein the volume of each does is about 20 mL and comprises about 40% w/v tagging agent. The motivation for doing so would have been that this low dosage would reduce the toxicity potential, and 40% w/w is a preferred concentration, as taught by Illig et al. (column 9, lines 28-46).

18. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of Johnson et al.. As discussed above, Vining et al. meet the limitations of claim 19. However, they do not specifically disclose that one or more food items comprises from about 0.01 g to about 150 g of the tagging agent. This is equivalent to about 10 mg to about 150,000 mg. Johnson et al. disclose using powdered or flaked barium administered to the patients in pill form (column 10, lines 50-53). They disclose that one group of patients received 600 mg of barium, which were administered with meals during the two days prior to the imaging procedure (column 10, lines 50-67). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Vining et al. to administer about 0.01 g to about 150 g of the tagging agent along with the food items. The motivation for doing so would have been that this amount has been shown to be capable of providing good quality tagged stool images, as taught by Johnson et al. (column 10, lines 62-67; also see Figure 22).

19. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. in view of Cittadel et al.. As discussed above, Vining et al. meet the limitations of claim 19. However, they do not specifically disclose that the individual's total fluid intake during the 24 hour administration is 1 to 3 liters. Cittadini et al. disclose that one group that received a large bowel cleansing preparation was administered 2 liters of water (pg. 217, Materials and Methods). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. to have the total fluid intake by the individual be about 1-3 liters. The motivation for doing so would have

been to provide oral hydration, as taught by Cittadini et al. (pg. 217, Materials and Methods).

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 7 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,866,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is well known in the art that a gastrointestinal procedure, such as colon screening, or sigmoidoscopy, would fall into the category of a predetermined activity that requires the tagging of at least

some colonic residue in the individual's tract, and may require the administration of a tagging agent.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SPE 3768